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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/382,186	08/23/1999	HANS J. HANSEN	018733/0942	4908

7590 06/18/2003

FOLEY AND LARDNER  
WASHINGTON HARBOR  
3000 K STREET, N.W.,  
SUITE 500  
WASHINGTON, DC 20007-5109

EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/18/2003

26

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

386,182

Applicant(s)

HANSEN et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 3/10/03
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 33-34, 37-48 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☒ Claim(s) 33-34, 37, 39-48 is/are allowed.
- ☒ Claim(s) 38 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1644

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/10/03 (Paper 25) has been entered.

Following entry of the amendment of 3/10/03, the claims pending and under examination are 33-34 and 37-48.

The amendment has overcome 112 issues of record pertaining to the now pending claims.

New 112 rejection is stated below.

Claim 38<sup>is</sup> rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.<sup>1</sup>

Claim 38 recites that the "at least one other arm that specifically binds a targetable conjugate is a humanized Fab fragment." To require that this arm be an Fab fragment is , however, inconsistent with base claim 33. Note that claim 33 recites, in parts (1) (B) and (2) (B), "forms a Fab fragment whose binding site is specific for said targeted tissue". For these parts of claim 33 to be consistent with what is recited in the preamble, the Fab of parts (1)(B) and (2)(B) must constitute the "at least one arm that specifically binds a targeted tissue" in the preamble. The only other available arm in the Fab-scFv fusion protein is thus the scFv, and this must, by the process of elimination, constitute the "at least one other arm that specifically binds a

Art Unit: 1644

targetable conjugate" in the preamble. What claim 38 requires is therefore inconsistent with base claim 33, which does not permit the "at least one other arm..." to be a Fab fragment.

Claims 33-34 and 37-48 are allowable over the prior art of record. The state of the art near to applicant's filing date is shown by van Spriel et al. (Immunology today, 21, 391, 2000). Figure 1(a) shows various bispecific antibodies known in the art. These include constructs containing two Fab arms (e.g. F(ab')<sub>2</sub> heterodimer) or two scFv arms (e.g. Sc-BsAb or diabody). The only construct having both scFv and Fab components also contains CH2 and CH3 domains, not encompassed by applicant's claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

June 12, 2003

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182/1644